EXPERT SYSTEM LICENSE EVALUATION
REPORT FOR LICENSE 04-00487-07 04-487-07 continuation of -04

NAME OF LICENSEE: US NAVAL RADIOLOGICAL DEFENSE LABORATORY
LISTED SITE: SCIENTIFIC DEPARTMENT, SAN FRANCISCO, CALIFORNIA
TYPE OF ACTIVITY OR FACILITY: MILITARY USE - NONREACTOR

Description of LICENSEE ACTIVITY UNDER THIS LICENSE

USE OF H-3, K-42, AND BR-82 IN HUMANS TO DETERMINE TOTAL BODY WATER AND EXCHANGE RATES.

****
THERE WAS DEFINITE OR POSSIBLE HUMAN USE FOR THIS LICENSE
INDICATION OF POSSIBLE OR DEFINITE NONROUTINE USE IN HUMANS
****

---------- MATERIALS INFORMATION FOR THIS LICENSE ----------

--Information on type and form of materials--

--Authorized Material--	--Form Authorized--
H-3	Loose or Any
BR-82	Loose or Any
K-42	Loose or Any

AMOUNT OR ACTIVITY OF THOSE MATERIALS CONTRIBUTING TO INITIAL SCORE:

---Material--	-SLD/LOOSE--	-ACTIVITY-	
H-3	LOOSE	.05079000	CI

SCORE FOR H-3 is either 0 or not available

BR-82	LOOSE	.00900000	CI

SCORE FOR BR-82 is either 0 or not available

K-42	LOOSE	.00300000	CI

SCORE FOR K-42 is either 0 or not available

FINAL DECISION FOR LOOSE MATERIALS:

POTENTIAL SITE CONTAMINATION:
ELIMINATED FROM CONSIDERATION SITE CONTAMINATION
Reason for elimination: LOW SOLUBILITY MATERIALS

SEQUENCE OF RECORDED REASONING

1. There was at least one sealed source on this license for which the amount remaining was reduced according to the length of the half-life

2. There was at least one loose material on this license for which the amount remaining was reduced according to the length of the half-life

3. FIRST SITE: The loose materials on this license were only short-lived materials, noble gases, or other materials which are not presently likely to produce significant contamination.

COMMENTS FOR LICENSE EVALUATION

Description of LICENSEE ACTIVITY UNDER THIS LICENSE

USE OF H-3, K-42, AND BR-82 IN HUMANS TO DETERMINE TOTAL BODY WATER AND EXCHANGE RATES.

- GENERAL COMMENTS ENTERED BY THE REVIEWER CONCERNING THE EVALUATION -
-- THE LICENSEE WAS AUTHORIZED 50 MILLICURIES OF HYDROGEN 3, 3
-- MILLICURIES OF POTASSIUM 42, AND 9 MILLICURIES OF BROMINE 82 IN THE
-- FORM OF WATER, POTASSIUM CHLORIDE, AND AMMONIUM BROMIDE RESPECTIVELY.
-- THESE MATERIALS WERE USED TO MEASURE THE TOTAL BODY WATER, TOTAL
-- EXCHANGEABLE POTASSIUM, AND TOTAL EXCHANGEABLE CHLORIDE
-- SIMULTANEOUSLY IN 60 ADULT HUMANS. MALE AND FEMALE VOLUNTEERS WERE
-- TESTED. THE REMAINING MATERIALS TAHT WERE NOT USED IN THE TESTING
-- WERE TRANSFERRED TO ANOTHER LICENSE (04-00487-03), WHICH WAS ALSO
-- HELD BY THE US NAVAL RADIOLOGICAL DEFENSE LABORATORY.

END OF COMMENTS FOR LICENSE EVALUATION

--- EXPERT SYSTEM EVALUATION WAS BASED ON THE ---
---- FOLLOWING INVENTORY RECORD -----
REGION RESPONSIBLE: V
LICENSEE NAME: US NAVAL RADIOLOGICAL DEFENSE LABORATORY
STREET ADDRESS: SCIENTIFIC DEPARTMENT City: SAN FRANCISCO
FIPS state code (principal operation): CA
Site used: SCIENTIFIC DEPARTMENT, SAN FRANCISCO, CALIFORNIA
Disposition information present: CERTIFICATE
Matl. Transfrd to: US NAVAL RADIOLOGICAL DEFENSE LAB.
License to which transferred: 04-00487-03
This license was listed as expired on 09/30/61

APPLICATION INFORMATION

There WAS a licensee application contained in the file
The application contained some information on material use.
GENERAL INVENTORY RECORD COMMENTS:
H-3, K-42, AND BR-82 USED TO MEASURE EXCHANGE RATES IN HUMANS.
JOB NUMBER: 1722 BOX NUMBER: 02

Date of last evaluation or revision: 06/30/94

WA Form 277
(4/59)

SEP 30 1961

CERTIFICATION OF STATUS OF RADIOISOTOPE (Byproduct Material) PROGRAM UNDER UNITED STATES ATOMIC ENERGY COMMISSION BYPRODUCT MATERIAL LICENSE

NO. 4-487-7

LICENSEE U. S. Naval Radiological Defense Laboratory
(Institution, firm, hospital, person, etc.)

ADDRESS San Francisco 24, California

DEPARTMENT(S) Biological and Medical Sciences Division

INDIVIDUAL RADIOISOTOPE USER(S) (b) (6), M. D.

The licensee and any individual executing this certification on behalf of the licensee certify that (check appropriate item(s) below):

____ No byproduct materials have been procured and/or possessed by licensee.

All byproduct materials procured and/or possessed by licensee under Byproduct Material License No. 4-487-7 have:

X (1) been transferred to U. S. Naval Radiological Defense Laboratory
(Institution, firm, hospital, person, etc.)
which has Byproduct Material License No. 4-487-3
(if known)

____ (2) been disposed of by decay.

____ (3) been disposed of in compliance with 10 CFR 20.

DUPLICATED FOR DIV. OF COMPLIANCE

8100739-61

(b) (6)

CERTIFYING OFFICIAL
Chairman, Radioisotope Committee

2 August 1961
DATE

Encl (1) to NRDL ltr 730-104 WJF:jp of

16—76439-1 U.S. GOVERNMENT PRINTING OFFICE

U. S. NAVAL RADIOLOGICAL DEFENSE LABORATORY
SAN FRANCISCO 24, CALIFORNIA

IN REPLY REFER TO FILE:
730-104
WJF:jp
4 AUG 1961

From: Commanding Officer and Director
To: U. S. Atomic Energy Commission (Division of Licensing and Regulation) Washington 25, D. C.
Via: Chief, Bureau of Ships (Code 362)

Subj: Expiration of License #4-487-7

Ref: (a) AEC ltr L&R:IB:37 (4-487-7) of 25 July 1961 to NRDL

Encl: (1) Certification of Status of Radioisotope (Byproduct Material) Program Under United States Atomic Energy Commission Byproduct Material License

1. Enclosure (1) is forwarded in accordance with reference (a) since this Laboratory does not plan to renew its "human-use license" #4-487-7.

2. Approximately 7 mc of tritiated water that was not used under this license is now held under our license #4-487-3.

(b) (6)

Copy to: (w/o encl)
BUMED (Code 74)

FORM AEC-374
(12-57)

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Part 30, Licensing of Byproduct Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, and is subject to all applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Name: Department of the Navy
2. Address: U. S. Naval Radiological Defense Laboratory, Scientific Department, San Francisco, California

3. License number: 4-487-7 (T61)
4. Expiration date: September 30, 1961
5. Reference No.: 4-487-4

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may posses at any one time.
A. Hydrogen 3	A. Water	A. 50 millicuries
B. Potassium 42	B. Potassium Chloride	B. 3 millicuries
C. Bromine 82	C. Ammonium Bromide	C. 9 millicuries

9. Authorized use

A., B. and C. Measurement of total body water, total exchangeable potassium, and total exchangeable chloride simultaneously in 60 adult humans.

CONDITIONS

10. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above.

11. The licensee shall comply with the provisions of Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation".

12. Byproduct materials shall be used by, or under the direct supervision of, (b) (6).

13. Byproduct material acquired from an Atomic Energy Commission facility shall not be used in humans until its pharmaceutical quality and assay have been independently established.

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For the U. S. Atomic Energy Commission

Original Signed By
(b) (6)
by (b) (6)
Chief, Isotopes Br
Division of Licensing and Regul
Washington 25, D. C.

Date September 21, 1959

5-21-59

(b) (6)

4-4187-7

Form AEC-313 (5-58)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved. Budget Bureau No. 38-R027.3.

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U. S. Atomic Energy Commission, Washington 25, D. C. Attention: Isotopes Branch, Division of Licensing and Regulation. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30 and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital, person, etc.)*

(b) (6) [redacted]
Chairman, Radioisotope Committee
U.S. Naval Radiological Defense Laboratory
San Francisco 24, California

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1 (a).)*

(1) USNRDL, San Francisco 24, California
(2) Los Alamos Scientific Laboratory
(3) U.S. Naval Hospital
Oak Knoll, California

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Scientific

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

4-487-4 (E59), Expires: 5/31/59

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

(b) (6) [redacted], LT (MC) USN
Radiological Health Officer

5. RADIATION PROTECTION OFFICER *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

(b) (6) [redacted]
Chairman, Radioisotope Committee

Ref: NRDL ltr 730-217 FTR:ams of 3 Dec 58 w/encl form 313 and supplements

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

Hydrogen 3
Potassium 42
Bromine 82

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*

Hydrogen 3 - tritiated water (HTO) - 50 mc
Potassium chloride solution - 3.0 mc
Ammonium bromide solution - 9.0 mc

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

See form 313a attached

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FOR DIV. OF INSP.

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(Continued on reverse side)

4-487-7

Form AEC-313 a (3-56)
PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-R080.

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME
(b) (6) , M.D., LT (MC) USN
U.S. Naval Radiological Defense Laboratory

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a))
(b) (6) , Chairman, Radioisotope Committee
U.S. Naval Radiological Defense Laboratory
San Francisco 24, California

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO. CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. CIRCLE ANSWER — (YES) NO

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

Measurement of total exchangeable Potassium, total exchangeable chloride, and total body water simultaneously in adult humans.

(b) CHEMICAL FORM ADMINISTERED:

(1) Potassium chloride
(2) Ammonium bromide
(3) Enriched tritiated water

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

(1) Handling will be done by trained personnel using NRDL equipment
(2) Storage will be in 2 inch lead shielding
(3) K^{42} and Br^{82} will decay away. H^3 waste will consist only of counting solutions.

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE
(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) CIRCLE ANSWER — (YES) NO

(2) ON FILE WITH THE ISOTOPES EXTENSION REFER TO APPLICATION NO See Application dated 3 Dec 1958 CIRCLE ANSWER — (YES) NO

5. PROPOSED DOSAGE SCHEDULE

(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

Br^{82} - .005 mc - .01 rad
K^{42} - .015 mc - .01 rad
H^3 - 0.3 mc - .02 rad

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) CIRCLE ANSWER — (YES) NO

See Supplement 1

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

See Supplement 2

20788

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. CIRCLE ANSWER — (YES) NO

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. CIRCLE ANSWER — (YES) NO

Form AEC-313 (5-58)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	U.S. Naval Radiological Defense Laboratory	6 mo.	(Yes) No	Yes (No)
b. Radioactivity measurement standardization and monitoring techniques and instruments	"	6 mo.	(Yes) No	Yes (No)
c. Mathematics and calculations basic to the use and measurement of radioactivity	"	6 mo.	(Yes) No	Yes (No)
d. Biological effects of radiation	"	6 mo.	(Yes) No	Yes (No)

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
K^{42}	3 mc	USNRDL	6 months	In vivo
Br^{82}	9 mc	USNRDL	6 months	In vivo
H^{3}	50 mc	USNRDL	6 months	In vivo

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm^2)	USE (Monitoring, surveying, measuring)
1) Plastic well scintillation counter	1	beta	See attached Form 313a		Measuring
2) NaI:Tl well scintillation counter	1	gamma	See attached Form 313a		Measuring
3) Pachard Tri-carb spectrometer	1	beta	See attached Form 313a		Measuring

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

Standard solution of long-lived isotopes

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

Film badges calibrated against radium and/or Cobalt 60 changed monthly. 0-200 mr pocket dosimeters used during handling of large quantities. Facilities for radio-analysis of urine available.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. *(Circle answer)* Yes No

Ref: Application dated 3 Dec 1958

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

Ref: Application dated 3 Dec 1958

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

Ref: Application dated 3 Dec 1958

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Date 6 May 1959

By: (b) (6) (b) (6) (b) (6)

Applicant named in Item 1

Chairman, Radioisotope Committee

Subscribed and sworn before me this 6 day of May 19

Title of certifying official (b) (6)

WARNING.—18 U. S. C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

GPO 93937